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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,673	07/20/2000	BRUCE PAUL DAGGY	C75087	9337

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,673	DAGGY ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 5/26/2006 is acknowledged.

Claims 19-34 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The examiner acknowledges applicant's request for an interview. However, due to time constraints, the examiner was unable to arrange for an interview. Applicant is invited to call the examiner to set up a time for an interview.

Claim Rejections Withdrawn:

4. The objection to claim 19 is withdrawn in view of the amendment.

5. The rejection of claims 19-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's arguments and in view of the amendment to the specification.

6. The rejection of claims 19-34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's arguments and

further in view of the amendment to the specification and the statement provided under 37 CFR 1.57(f).

Claim Rejections Maintained and New Grounds of Rejection:

7. Claims 19-34 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection is that one of skill in the art cannot use the specification to make or use the claimed inventions without undue experimentation.

Applicant's arguments have been carefully considered but fail to persuade. Applicant points to an experiment shown in the specification that demonstrates an effect of methylcellulose on aberrant crypt foci (ACF) formation in rats that had been injected with azoxymethane (a carcinogen). However, in view of the state of the art that indicates that animal models do not correlate with human epidemiological data (teachings of Baron, discussed in previous Office action), it appears that the guidance provided by the specification is insufficient to support the claimed methods, where the intended use of the claimed methods is for the prevention of either colon cancer or breast cancer. Applicant also argues that because Baron is published 6 years later than the filing date of this application, it is not prior art to the instant application and that it is not valid to use it in a rejection of the claims. However, applicant is reminded that in a rejection under 35 U.S.C. 112, first paragraph, the Office may cite references with a publication date that is after the filing date of the application if the reference cited is for the purpose of

demonstrating what one of skill in the art would have known at the time the application was filed. "In general, the examiner should not use post-filing date references to demonstrate the patent is non-enabling. Exceptions to this rule could occur if a later-dated reference provides evidence of what one skill in the art would have known on or before the effective filing date of the patent application." See MPEP 2164.05(a). In this case, a comparison was made between the claims, which are drawn to treatment of humans, and the data provided in the specification, which is from a rat model. Baron teaches that animal models to do not correlate with human epidemiological data. Therefore, Baron provides evidence that data provided in the specification would not lead one of skill in the art to have a reasonable expectation of success in practicing the methods as claimed for the purpose of preventing colon cancer or breast cancer in humans.

The examiner acknowledges the references provided by applicant in the response and notes that the Davis abstract appears to present data that is the same as that found in the specification, and that the Yokoyama reference does not present any data having to do with the intended use of the claimed methods, which intended use is the prevention of colon cancer or the prevention of breast cancer. Therefore, it does not appear that applicant has provided any references or arguments that rebut the teachings of Baron.

Additionally, it is noted that in the previous Office action, the examiner discussed the lack of support in the specification for the intended use of prevention of breast cancer. The experiment pointed to by applicant in the response is an experiment to examine the effect of fiber on the development of colorectal cancer (because the endpoint measured was the number of abberant crypt foci). Thus, the specification also does not appear to provide guidance with respect to effect of methylcellulose and prevention of breast cancer, because the working

example is directed to prevention of colorectal cancer in rats. Additionally, as discussed in the previous Office action, in the art, there appears to be a lack of consensus for the effect of fiber in general and no information with regard to the specific fiber, methylcellulose and the prevention of breast cancer. One study reports no effect of dietary fiber and the prevention of breast cancer (see Cho, W. et al. Cancer Epidemiology, Biomarkers & Prevention, 12: 1153-1158, 2003; page 1153, abstract and also 2nd column, 2nd paragraph). Another study does support an effect of dietary fiber in general (see Mattisson, I., et al., British Journal of Cancer , 90: 122-127, 2004; page 122, abstract), however, the results are for dietrary fiber in general and not specifically to methylcellulose. Dietary fiber is often ingested in the form of whole grains and the protective effect of ingesting fiber may be related to other nutrients found in whole grains and not merely to presence of fiber. Slavin (Slavin, J., Proc. Nutr. Soc., 62(1): 129-134, 2003; abstract only) teaches that whole grains are sources of fiber, and additionally antioxidants, trace minerals, phenolic compounds, phytate, and phyto-estrogens, which are also nutrients associated with disease prevention.

Therefore, the rejection of record is maintained.

8. Claims 19-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno (U.S. Patent 4,017,598; filing date Apr. 12, 1977) in view of ALVA-AMCO (Copy of Consumer Packaging of ALVA-Amco Pharmacal Cos., Inc.'s Fibre Naturale, 1996).

The claims are drawn to methods of administering methylcellulose at a viscosity of 4000 centipoise. The specification, as currently amended, teaches an example of methylcellulose having a mean viscosity of 4000 centipoise, with a range of 3000 to about 5,600. In light of the

fact that viscosity can change with temperature and other conditions, and in light of the fact that the claims do not recite the conditions under which the viscosity is determined, the phrase in the claims of "having a viscosity of 4000 centipoise" is interpreted to include viscosities that are near to 4000 centipoise (such as, for example, "4,350 centipoise").

Ohno teaches methylcellulose preparations of readily disintegrable tablets, where the viscosity of the 2% by weight aqueous solution methylcellulose is 4,350 centipoise at 20°C. Ohno also teaches pharmaceutically acceptable carriers or diluents, tablet forms, comprising sugar, sucrose, and talc (see col. 4, lines 10-18; column 3, lines 6-27 and lines 44-68). Ohno clearly teaches that the methylcellulose preparations are intended for administration to humans (see col. 1, lines 26-39). Ohno fails to teach specific daily dosages. However, ALVA-AMCO teaches that recommended daily dosages of methylcellulose preparations are in the range of 1800 mg to 2700 mg (6 to 9 caplets daily, each caplet having 300 mg methycellulose). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the Ohno methylcellulose preparations in a method of administration to a human, because Ohno clearly teaches that the methylcellulose preparations are intended for human consumption.

In previous Office actions, applicant has argued that rejections over the prior art are not valid because the prior art did not teach that the method of administration was useful for reduction of the incidence of colorectal cancer or breast cancer. This argument is not persuasive, because the claims and the prior art cited have the same active steps and the same population of people (healthy human beings) is being treated. Therefore, it appears that the intended use of the

claimed methods does not alter the active method steps, the population being treated or the product being used in the claimed methods.

9. Claims 19-34 are rejected under 35 U.S.C. 103(a) as being obvious over Daggy (U.S. 6,350,469; issued Feb. 26, 2002; effective filing date Aug. 22, 1997).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Daggy teaches rapidly disintegrating methylcellulose tablet formulations of methylcellulose, where the viscosity is greater than 4000 centipoise, or is Dow Methocel A4M having a viscosity of about 3000 to about 5,600 centipoise (column 2, line 45 to column 3, line22). Daggy also teaches pharmaceutically acceptable carriers or diluents, tablet forms,

comprising magnesium stearate, sugar, gelatin, acacia or agar (see col. 4, line 62 to column 5, line 21). Daggy clearly teaches that the methylcellulose preparations are intended for administration to humans (see col. 2, lines 31-39). Daggy teaches specific daily dosages that are within the range of those claimed (see column 5, lines 22-40). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the Daggy methylcellulose preparations in a method of administration to a human, because Daggy clearly teaches that the methylcellulose preparations are intended for human consumption.

In previous Office actions, applicant has argued that rejections over the prior art are not valid because the prior art did not teach that the method of administration was useful for reduction of the incidence of colorectal cancer or breast cancer. This argument is not persuasive, because the claims and the prior art cited have the same active steps and the same population of people (healthy human beings) is being treated. Therefore, it appears that the intended use of the claimed methods does not alter the active method steps, the population being treated or the product being used in the claimed methods.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 38 and 40 of copending Application No. 10/123,569. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of claims 38 and 40 comprise administering a tablet of claim 1, which encompasses a tablet of claim 32, which is a rapidly disintegrating tablet comprising methylcellulose of a viscosity of > 4000 centipoise as the sole active ingredient (claim 1 recites that the viscosity is >1000 centipoise), and the instant claims are drawn to methods of treating humans consisting essentially of, in part, administering methylcellulose of viscosity that is 4000 centipoise. Claims 38 and 40 of copending Application No. 10/123,569 are drawn to methods of treating mammals for constipation, but the specification sets forth, on page 6, lines 27-36, that the tablets will be administered to humans. Because the active steps of the methods of claims 38 and 40 are the same as the active steps of the instant methods, the methods of claims 38 and 40 anticipate the methods of the instant application even though the intended uses of the methods are different.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
August 1, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER